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New Drug Application (NDA): 204031

Company: MALLINCKRODT INC

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- **Medication Guide** (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204031s004s005lbl.pdf#page=34)

Products on NDA 204031

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
XARTEMIS XR	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	325MG;7.5MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 204031



Original Approvals or Tentative Approvals

CSV	Excel	Print
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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
03/11/2014	ORIG-1	Approval	Type 3 - New Dosage Form	PRIORITY	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/018121Orig1s01Label.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/018121Orig1s01Letter.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/018121Orig1s01Review.pdf)

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Supplements

CSV	Excel	Print
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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
09/18/2018	SUPPL-5	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/018121Suppl5Label.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/018121Suppl5Letter.pdf)
09/18/2018	SUPPL-4	REMS - PROPOSAL - D-N-A	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/018121Suppl4Label.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/018121Suppl4Letter.pdf)
12/16/2016	SUPPL-3	Labeling- Package Insert, Labeling- Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/018121Suppl3Label.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/018121Suppl3Letter.pdf)
03/12/2015	SUPPL-1	Labeling- Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/018121Suppl1Label.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/018121Suppl1Letter.pdf)

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
01/26/2015	SUPPL-2	Manufacturing (CMC)	

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Labels for NDA 204031

